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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,024	03/12/2004	Kathleen Aertgeerts	SYR-HSD11B1-5001-C1	6784

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TAKEDA SAN DIEGO, INC.
10410 SCIENCE CENTER DRIVE
SAN DIEGO, CA 92121

EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	**PAPER NUMBER**
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,024	AERTGEERTS ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413). Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 25-32, 49, 50 and 55, drawn to a composition comprising a protein crystal of a HSD11B1 with at least 90% identity to amino acids 24-292 of SEQ ID No: 1, methods of making therefor, and a composition of the isolated protein thereof consisting of amino acids 24-292 of SEQ ID No: 1 or with a His-tag (SEQ ID No: 5), classified in class 435, subclass 183.

II. Claims 9-16, 33-40, 51, 52 and 56, drawn to a composition comprising a protein crystal of a HSD11B1 with at least 90% identity to amino acids 24-258 of SEQ ID No: 1, methods of making therefor, and a composition of the isolated protein thereof consisting of amino acids 24-268 of SEQ ID No: 1 or with a His-tag (SEQ ID No: 6), classified in class 435, subclass 183.

III. Claims 17-24, 41-48, 53, 54 and 57, drawn to a composition comprising a protein crystal of a HSD11B1 with at least 90% identity to amino acids 24-267 of SEQ ID No: 1, methods of making therefor, and a composition of the isolated protein thereof consisting of amino acids 24-267 of SEQ ID No: 1 or with a His-tag (SEQ ID No: 7), classified in class 435, subclass 183.

IV. Claims 58-64, drawn to methods of performing rational drug design based on the 3-D coordinates obtained from the crystal having at least 90% identity to amino acids 24-292 of SEQ ID No: 1, classified in class 703, subclass 11.

V. Claims 65-71, drawn to methods of performing rational drug design based on the 3-D coordinates obtained from the crystal having at least 90% identity to amino acids 24-258 of SEQ ID No: 1, classified in class 703, subclass 11.

VI. Claims 72-78, drawn to methods of performing rational drug design based on the 3-D coordinates obtained from the crystal having at least 90% identity to amino acids 24-267 of SEQ ID No: 1, classified in class 703, subclass 11.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-III are directed to related distinct products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed for each protein crystal is made of a distinct protein sequence which subsequently forms into distinct protein crystal space groups, e.g. space group $P2_1$, $P3_121$ and $P4_12_12_1$ (for Groups I-III respectively), which have unique unit cell parameters and unique conditions to induce crystal growth. Thus each crystal is unique

and distinct from the other and each crystal cannot be said to be an obvious variation of the others because there is no known way to induce a particular crystal space group to form for any given crystal. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Thus, there would not necessarily be a co-extensive search for each patentably distinct product which would be burdensome to the examiner.

3. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a materially different process such as an *in vitro* assay to determine products that bind. Alternatively, the crystal could be soaked in a series of agonists or antagonists and subsequently solving each structure to determine products that bind or do not bind.

4. Inventions I and V-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not related because the methods of Groups V-VI do not use the crystal structure coordinated obtained from the crystal product of Group I, rather the methods each use the coordinates obtained from unique and patentably distinct crystal

products of Groups II and III, respectively. As such there would not be a co-extensive search which would place an undue search burden placed on the examiner.

5. Inventions II and (IV and VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not related because the methods of Groups (IV and VI) do not use the crystal structure coordinated obtained from the crystal product of Group II, rather the methods each use the coordinates obtained from unique and patentably distinct crystal products of Groups I and III, respectively. As such there would not be a co-extensive search which would place an undue search burden placed on the examiner.

6. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a materially different process such as an *in vitro* assay to determine products that bind. Alternatively, the crystal could be soaked in a series of agonists or antagonists and subsequently solving each structure to determine products that bind or do not bind.

7. Inventions III and IV-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs,

modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not related because the methods of Groups IV-V do not use the crystal structure coordinated obtained from the crystal product of Group III, rather the methods each use the coordinates obtained from unique and patentably distinct crystal products of Groups I and II, respectively. As such there would not be a co-extensive search which would place an undue search burden placed on the examiner.

8. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be used in a materially different process such as an *in vitro* assay to determine products that bind. Alternatively, the crystal could be soaked in a series of agonists or antagonists and subsequently solving each structure to determine products that bind or do not bind.

9. Inventions IV-VI are directed to related distinct processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed used patentably distinct crystal products to obtain 3-D data which is used to achieve the end result of the rational drug design (e.g. compounds that bind

each individual protein). Thus, the materials used in each method involves different 'products' and thus have a different mode of operation, design and function. Additionally, the inventions are not considered to be obvious variants of one another. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

10. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.00am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suzanne M. Noakes

SMN
14 December 2006